K130160

STERIS®

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510(k) Summary
For

AUG 16 2013

VERIFY™ Process Indicator for Reliance™ Endoscope Processing Systems

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Summary Date: August 7, 2013

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1. Device Name

Trade Name:	VERIFY Process Indicator for Reliance Endoscope Processing Systems
Common/usual Name:	Indicator, Physical/Chemical Sterilization Process
Classification Name:	21 CFR 880.2800 Sterilization Process Indicator
Device Class:	II
Product Code:	JOJ

2. Predicate Device

Reliance CI Process Indicator – **K063285**
marketed as VERIFY Process Indicator for Reliance Endoscope Processing System

3. Description of Device

The VERIFY Process Indicator for Reliance Endoscope Processing Systems is a single-use chemical indicator strip with indicator ink printed on one end that monitors the peracetic acid (PAA) dose at the point of use in a Reliance EPS Endoscope Processing System or a Reliance Advance Endoscope Processing System employing Reliance DG Dry Germicide.

The process indicator shows an incomplete color change when exposed to peracetic acid at a dose of $\leq$ 9000 mg/L PAA min. in an Endoscope Processing Cycle. It shows a complete color change from orange to white (colorless) when exposed to peracetic acid at a dose of $\geq$ 11,500 mg/L PAA min. in an Endoscope Processing Cycle.

The chemical indicator performs equivalently in Reliance Endoscope Processing System (EPS) and in Reliance Advance Endoscope Processing System.

4. Intended Use

The VERIFY Process Indicator for Reliance Endoscope Processing Systems is intended for routine monitoring of the Reliance Endoscope Processing System (EPS) and the Reliance Advance Endoscope Processing System employing Reliance DG Dry Germicide. The device is a peracetic acid dose indicator that changes color from orange to white (colorless) upon exposure to an effective dose of peracetic acid.

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5. Description of Safety and Substantial Equivalence

The characteristics and technology of the proposed VERIFY Process Indicator for Reliance Endoscope Processing Systems described in this submission are physically identical to those for the predicate. This submission demonstrates that the performance of the subject indicator in the proposed Reliance Advance Endoscope Processing System is equivalent to its performance in the original Reliance Endoscope Processing System. The proposed new indication does not raise any new concerns of safety and effectiveness.

6. Comparison of Technological Characteristics

Feature	VERIFY PI for Reliance EPS (proposed)	VERIFY PI for Reliance EPS (STERIS predicate K063285)
Substrate	same	Polypropylene
Indicator	same	Ink overlaid with clear, permeable laminate
Color change	same	Orange to colorless
Shelf life	same	12 months
Storage conditions	same	6°C (43°F) - 30°C (86°F) and 30-80% RH
Use and disposal	same	Single use, disposable
Active monitored	same	Peracetic acid (PAA) dose
Response to PAA dose of:		
≥11,500 mg/L PAA min.	same	Colorless[1]: **Pass**
≤9000 mg/L PAA min.	same	Incomplete color change[2]: **Fail** (not as light as Pass color)
none	same	Orange (Start color, unprocessed)

[1]The Pass endpoint color is actually the absence of color, which appears dull white against the bright white color of the strip on which the indicator ink is printed.

[2]Any shade of orange or any color other than the reference Pass color.

7. Performance Testing

Performance testing was conducted to demonstrate that the VERIFY Process Indicator for Reliance Endoscope Processing Systems is an effective monitor for the circulating peracetic acid dose provided in the Reliance Advance Endoscope Processing System employing Reliance DG Dry Germicide.

The performance of the VERIFY Process Indicator for Reliance Endoscope Processing Systems in the Reliance Advance Endoscope Processing System, as summarized below, is substantially equivalent to its performance in the predicate Reliance Endoscope Processing System.

Performance Testing Summary

Test	Acceptance Criteria	Result
Unprocessed Cl strip	Color matches the orange 'start' color block on the bottle label prior to use	PASS
Response to PAA dose ≥ 11,500 mg/L PAA min	Colorless (complete change, Pass) at end of the Reliance Advance Endoscope Processing Cycle	PASS
Response to PAA dose ≤ 9000 mg/L PAA min	NOT colorless (incomplete change, Fail) at end of the Reliance Advance Endoscope Processing Cycle using the minimum effective dose PAA, or with no PAA	PASS
Stability	After 12 months storage in each of three test environments, the product correctly indicated Pass and Fail in cycles of corresponding PAA dose.	PASS
Opened bottle use life	Opened PI containers stored in each of three test environments were re-opened repeatedly for 6 months and tested. The PI from the opened bottles correctly indicated Pass and Fail in cycles of corresponding PAA dose through 6 months.	PASS
Endpoint color stability	Reliance PIs processed through cycles of Pass and Fail PAA dose levels, evaluated after processing and read again 6 months later, each gave the same outcome. The end color is stable for 6 months.	PASS

Conclusion:

The completed nonclinical performance testing has demonstrated that the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 16, 2013

STERIS Corporation
Ms. Marcia L. Benedict
Senior Director, Regulatory Affairs
5960 Heisley Road
MENTOR OH 44060

Re: K130160
Trade/Device Name: VERIFY Process Indicator for Reliance Endoscope Processing Systems
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: July 29, 2013
Received: August 1, 2013

Dear Ms. Benedict:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130160

Device Name: VERIFY Process Indicator for Reliance Endoscope Processing Systems

Indications For Use:

The VERIFY Process Indicator for Reliance Endoscope Processing Systems is intended for routine monitoring of the Reliance Endoscope Processing System (EPS) and the Reliance Advance EPS employing Reliance DG Dry Germicide. The device is a peracetic acid dose indicator that changes color from orange to white (colorless) upon exposure to an effective dose of peracetic acid.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
2013.08.09 11:35:18 -04'00'

Division Sign-Off)
vision of Anesthesiology, General Hospital
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